

CLAIMS

What is claimed is:

- 1 1. A heat exchange/intra-aortic counterpulsation catheter device comprising:
2 an elongate catheter having a proximal end and a distal end, said catheter being
3 advancable, distal-end-first, into the aorta of a human or veterinary patient;
4 a counterpulsation balloon useable for effecting intra-aortic balloon
5 counterpulsation; and,
6 a heat exchanger useable to cool at least a portion of the patient's body to a
7 temperature that is at least 1 °C below normothermia.
- 1 2. A device according to Claim 1 wherein the heat exchanger comprises a heat
2 exchanger through which heat exchange fluid is circulated.
- 1 3. A device according to Claim 2 wherein said heat exchanger comprises a heat
2 exchange balloon.
- 1 4. A device according to Claim 3 wherein the heat exchanger comprises a single-
2 lobed heat exchange balloon.
- 1 5. A device according to Claim 3 wherein the heat exchanger comprises a multi-lobed
2 heat exchange balloon.
- 1 6. A device according to Claim 1 wherein at least a portion of the heat exchanger is
2 metallic.

1 7. A device according to Claim 3 wherein the heat exchange balloon and the
2 counterpulsation balloon comprise a single balloon that is useable for both
3 counterpulsation and heat exchange.

1 8. A device according to Claim 1 wherein the heat exchanger comprises a heat
2 exchange surface and wherein the device further comprises a flow disruption surface
3 associated with the heat exchange surface, the flow disruption surface being configured
4 to disrupt the laminarity of blood flow adjacent to the heat exchange surface, thereby
5 enhancing the efficiency by which the heat exchanger exchanges heat with the flowing
6 blood.

1 9. A device according to Claim 1 wherein the counterpulsation balloon is positioned
2 at a first location on the catheter and the heat exchanger comprises a heat exchange
3 surface located at a second location on the catheter.

1 10. A device according to Claim 9 wherein the first location is closer to the distal end of
2 the catheter than the second location.

1 11. A device according to Claim 9 wherein the second location is closer to the distal
2 end of the catheter than the first location.

1 12. A device according to Claim 9 wherein the heat exchanger and the counterpulsation
2 balloon comprise a single balloon which is a) configured and useable to effect intra-aortic
3 counterpulsation and b) receives a heat exchange medium such that heat is exchanged
4 between the heat exchange medium and the blood, through at least a portion of the
5 balloon.

1 13. A system comprising a heat exchange/intra-aortic counterpulsation catheter device
2 according to Claim 1, further in combination with:

3 apparatus attachable to the catheter and useable to cause a) inflation and deflation
4 of the counterpulsation balloon in response to the patient's cardiac cycle to effect intra-
5 aortic balloon counterpulsation that results in a beneficial effect on the patient and b) at
6 least cooling (and preferable cooling or heating) of the heat exchanger to cause cooling of
7 at least a portion of the patient's body (e.g., the heart) to a temperature that is at least 1
8 °C below normothermia.

1 14. A method for treating a human or veterinary patient who suffers from congestive
2 heart failure or another condition wherein the patients cardiac output is subnormal, said
3 method comprising the steps of:

- 4 a. providing a heat exchange/intra-aortic counterpulsation catheter comprising
5 i) an elongate catheter having a proximal end and a distal end, said catheter
6 being advancable, distal-end-first, into the aorta of the patient, ii) a
7 counterpulsation balloon useable for effecting intra-aortic balloon
8 counterpulsation; and, a heat exchanger useable to cool at least a portion of
9 the patient's body to a temperature that is at least 1 °C below normothermia.
10 b. advancing the heat exchange/intra-aortic counterpulsation catheter, distal
11 end first, into the patient's aorta such that the counterpulsation balloon is
12 positioned in the thoracic aorta;
13 c. driving and controlling the counterpulsation balloon and heat exchanger so
14 as to effect intra-aortic balloon counterpulsation while cooling and/or
15 maintaining the temperature of at least a portion of the patient's body to a
16 temperature that is at least 1 °C below normothermia.

1 15. A method according to Claim 14 further comprising the step of:

- 2 d. administering an antishivering treatment tot he patient.

1 16. A method according to Claim 14, wherein the patient's body temperature is cooled
2 to and maintained within the range of 32-34°C while intra-aortic counterpulsation is
3 performed.

1 17. A method according to Claim 15 wherein the anti-shivering treatment is selected
2 from the group of anti-shivering treatments consisting of: i) administering a therapeutically
3 effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of
4 the donor and iii) administering a therapeutically effective amount of an anti-shivering agent
5 to the donor and applying warmth to the skin of the donor.

1 18. A method according to Claim 15 wherein the anti-shivering treatment comprises
2 administering to the donor a therapeutically effective amount of at least one anti-shivering
3 agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine
4 receptor agonists; iii) κ -opioid receptor agonists; iv) opioid agonist-antagonist analgesics;
5 v) serotonin 5HT1a receptor agonists and vi) alpha-2 adrenergic receptor agonists.

1 19. A method for treating a human or veterinary patient who suffers from congestive
2 heart failure or another condition wherein the patients cardiac output is subnormal, said
3 method comprising the steps of:

- 4 a. providing a heat exchange catheter comprising i) a heat exchange catheter
5 body and ii) at least one heat exchanger for exchanging heat with blood
6 flowing through a blood vessel into which the heat exchange catheter body
7 is inserted;
- 8 b. providing an intra-aortic balloon counterpulsation catheter comprising i) a
9 counterpulsation catheter body and ii) a counterpulsation balloon useable
10 for effecting intra-aortic balloon counterpulsation;
- 11 c. inserting the heat exchange catheter into the patient's vasculature such that
12 blood flows in heat exchange proximity to the heat exchanger;

- d. inserting the intra-aortic balloon counterpulsation catheter into the patient's vasculature such that the counterpulsation balloon is positioned within the patient's aorta;
- e. using the intra-aortic balloon counterpulsation catheter to effect intra-aortic balloon counterpulsation; and,
- f. using the heat exchange catheter to cool the temperature of at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

20. A method according to Claim 19 further comprising the step of:

- g. administering an antishivering treatment to the patient.

21. A method according to Claim 20 wherein the wherein the anti-shivering treatment is selected from the group of anti-shivering treatments consisting of: i) administering a therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of the donor and iii) administering a therapeutically effective amount of an anti-shivering agent to the donor and applying warmth to the skin of the donor.

22. A method according to Claim 20 wherein the anti-shivering treatment comprises administering to the donor a therapeutically effective amount of at least one anti-shivering agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine receptor agonists; iii) κ -opioid receptor agonists; iv) opioid agonist-antagonist analgesics, v) serotonin 5HT_{1a} receptor agonists and vi) alpha-2 adrenergic receptor agonists.

23. A method according to Claim 19, wherein the patient's body temperature is cooled to and maintained within the range of 32-34°C while intra-aortic counterpulsation is performed.

24. A method according to Claim 19 wherein the heat exchanger is positioned in a vein.

1 25. A method according to Claim 24 wherein the heat exchanger is positioned in the
2 vena cava.